jc614 U.S. PTO 11/10/98

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	98-5295
Total Pages	
First Named Inventor or Application Identifier	J.T. Lin
Express Mail Label No.	

jc542 U.S. PTO 09/189609 11/10/98

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Assistant Commissioner for Patents**
Box Patent Application
Washington, DC 20231

1. [X] Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. [X] Specification [*Total Pages* 22]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (*if filed*)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [X] Drawing(s) *(35 USC 113)* [*Total Sheets* 3]

4. Oath or Declaration [*Total Pages*]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 17 completed)
   [Note Box 5 below]
   i. [ ] DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. [ ] Incorporation By Reference *(useable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. [ ] Microfiche Computer Program *(Appendix)*

7. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. [ ] Assignment Papers (cover sheet & document(s))
9. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
10. [ ] English Translation Document *(if applicable)*
11. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
12. [ ] Preliminary Amendment
13. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. [X] Small Entity Statement(s) [ ] Statement filed in prior application, Status still proper and desired
15. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. [ ] Other: .....

17. **If a CONTINUING APPLICATION,** *check appropriate box and supply the requisite information:*
[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____

18. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

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FEE TRANSMITTAL

Note: Effective October 1, 1997.
Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 439.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	J.T. Lin
Group Art Unit	
Examiner Name	
Attorney Docket Number	98-5295

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number
Deposit Account Name

☐ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☐ Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance

2. ☒ Payment Enclosed:
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FEE CALCULATION

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	395
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 395.00

2. CLAIMS

		Extra		Fee from below		Fee Paid
Total Claims	24 -20 =	4	X	11	=	44
Independent Claims	3 - 3 =		X		=	
Multiple Dependent Claims			X		=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	82	209	41	Reissue independent claims over original patent
110	22	210	11	Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 44.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	950	217	475	Extension for reply within third month	
118	1,510	218	755	Extension for reply within fourth month	
128	2,060	228	1,030	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,320	241	660	Petition to revive - unintentional	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	William M. Hobby, III			Reg. Number	24,167
Signature		Date	11-6-98	Deposit Account User ID	

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional) 98-5295

Applicant, Patentee, or Identifier: J.T. Lin

Application or Patent No.:

Filed or Issued:

Title: TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING A DUAL-LASER SCANNING SYSTEM

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

[X] the specification filed herewith with title as listed above.

[ ] the application identified above.

[ ] the patent identified above.

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Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

J.T. Lin		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of inventor	Signature of inventor	Signature of inventor
11-6-98		
Date	Date	Date

TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING A DUAL-LASER SCANNING SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and apparatus for the treatment of presbyopia and the treatment and prevention of glaucoma using dual-beam scanning lasers.

2. Prior Art

Corneal reshaping, including a procedure called photorefractive keratectomy (PRK) and a new procedure called laser assisted in situ keratomileusis, or laser intrastroma keratomileusis (LASIK), has been performed by lasers in the ultraviolet (UV) wavelength of 193 - 213 nm. Commercial UV refractive lasers include ArF excimer lasers at 193 nm and other non-excimer, solid-state lasers, such as the one patented by the present inventor in 1992 (U.S. Patent No. 5,144,630). Precise, stable corneal reshaping requires lasers with strong tissue absorption (or minimum penetration depth) such that the thermal damage zone is at a minimum (less than few microns). Furthermore, accuracy of the procedure of vision correction depends on the amount of tissue removed in each laser pulse, in the order of about 0.2 microns. Therefore, lasers at UV wavelengths between 193 and 213 nm and at the mid-infrared wavelengths between 2.8 and 3.2 microns are two attractive wavelength ranges which match the absorption peak of protein and water, respectively.

The above-described prior arts are however limited to the use of reshaping the corneal surface curvature for the correction of myopia and hyperopia.

A variation of farsightedness that the existing laser surgery procedures will not treat is presbyopia, the gradual age related condition of suddenly fuzzy print and the necessity of reading glasses. When a person reaches a certain age (around 40), the eyes start to lose their capability to focus sharply for near vision. Presbyopia is not due to the cornea but comes about as the lens loses its ability to accommodate or focus sharply for near vision as a result of loss of elasticity that is inevitable as people age.

Thermal lasers such as Ho:YAG have been proposed for the correction of hyperopia by laser-induced coagulation of the corneal. The present inventor has also proposed the use of a laser-generated bifocal for the treatment of presbyopic patients but fundamental issues caused by age of presbyopic patients still remains unsolved in those prior approaches.

To treat presbyopic patients, or the reversal of presbyopia, using the concept of expanding the sclera by mechanical devices has been proposed by Schaker in U.S. patents 5,529,076, 5,722,952, 5,465,737 and 5,354,331. These mechanical approaches have the drawbacks of complexity and are time consuming, costly and have potential side effects. To treat presbyopia, the Schaker patents Nos. 5,529,076 and 5,722,952 propose the use of heat or radiation on the corneal epithelium to arrest the growth of the crystalline lens and also propose the use of lasers to ablate portions of the thickness of the sclera. However, these prior arts do not present any details or practical methods or laser parameters for the presbyopic corrections. No clinical studies have been practiced to show the effectiveness of the proposed concepts. The concepts proposed in the Schaker

patents regarding lasers suitable for expanding the sclera tissues were incorrect in that the proposed lasers did not identify those which are "cold lasers" and can only conduct the tissue ablation rather than thermal burning of the cornea. Furthermore, the clinical issues, such as accuracy of the sclera tissue removal and potential tissue bleeding during the procedures, were not indicated in these prior patents. In addition, it is essential to use a scanning laser to achieve the desired ablation pattern and to control the ablation depth on the sclera tissue.

One objective of the present invention is to provide an apparatus and method to obviate these drawbacks in the above Schaker patents.

It is yet another objective of the present invention to provide an apparatus and method which provide the well-defined laser parameters for efficient and accurate sclera expansion for presbyopia reversal and the treatment and preventing of open angle glaucoma.

It is yet another objective of the present invention to use a scanning device such that the degree of ciliary mussel accommodation can be controlled by the location, size and shapes of the removed sclera tissue.

It is yet another objective of the present invention to define the non-thermal lasers for efficient tissue ablation and thermal lasers for tissue coagulation. This system is able to perform both in an ablation mode and in a coagulation mode for optimum clinical outcomes. It is yet another objective of the present invention to provide an integrated system in which dual-beam lasers can be scanned over the corneal surface for accurate ablation

of the sclera tissue without bleeding, with ablation and coagulation laser beams simultaneously applied on the cornea.

It is yet another objective of the present invention to define the optimal laser parameters and the ablation patterns for best clinical outcome for presbyopia patients, where sclera expansion will increase the accommodation of the ciliary mussel.

It is yet another objective of the present invention to provide the appropriate scanning patterns which will cause effective sclera expansion.

SUMMARY OF THE INVENTION

The preferred embodiments of the present surgical laser consists of a combination of an ablative-type laser and a coagulative-type laser. The ablative-type laser has a wavelength range of from 0.15 to 0.35 microns and from 2.6 to 3.2 microns and is operated in a Q-switch mode such that the thermal damage of the corneal tissue is minimized. The coagulative-type lasers includes a thermal laser having a wavelength of between 0.45 and 0.9 microns and between 1.5 and 3.2 microns, and between 9 and 12 microns operated at a long-pulse or continuous-wave mode.

It is yet another preferred embodiment of the present invention to provide a scanning mechanism to effectively ablate the sclera tissue at a controlled depth by beam overlapping.

It is yet another preferred embodiments of the present invention to provide an apparatus and method such that both the ablative and the coagulative lasers can have applied to their beams the corneal surface to thereby prevent bleeding during the procedure.

It is yet another embodiment of the present invention to provide an integration system in which a coagulative laser may have the beam delivered by a scan or by a fiber-coupled device which can be manually scanned over the cornea. It is yet another embodiment of the present invention to focus the laser beams in a small circular spot or a line pattern.

It is yet another embodiment of the present invention to provide a coagulative laser to prevent the sclera tissue bleeding when a diamond knife is used for the incision of the sclera.

It is yet another embodiment of the present invention to use a metal mask on the corneal surface to generate a small slit when the laser is scanning over the mask. In this embodiment, the exact laser spot size and its propagating stability are not critical.

It is yet another embodiment of the present invention to provide an integration system in which the sclera expansion leads to the increase of the accommodation of the ciliary muscle for the treatment of presbyopia and the prevention of open angle glaucoma.

Further preferred embodiments of the present invention will become apparent from the description of the invention which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of an integrated laser system consisting of two lasers of different wavelengths coupled to the cornea by mirrors and a scanning device;

Figure 2 is a block diagram of a laser system where the coagulative laser is fiber-coupled and manually delivered to the cornea;

Figure 3 is the schematic drawing of the anteroposterior section through the anterior portion of a human eye, where the sclera and ciliary muscle are shown; and

Figures 4A-4D are diagrams of the possible ablation patterns which will achieve a presbyopia-reversal.

DETAILED DESCRIPTION OF THE INVENTION AND THE PREFERRED EMBODIMENTS

Figure 1 of the drawings is a schematic of a laser system having an ablative laser 1 producing a laser beam 2 of a predetermined wavelength and focused by a lens 3 onto a reflecting mirror 4 which is coupled to another reflecting mirror 5. The system also consists of a coagulation laser 6 having a laser beam 7 of a predetermined wavelength focused by a lens 3A through a mirror 5. The ablation laser 1 beam 2 and the coagulation laser 6 beam 7 are directed onto a scanner 8. The beams 2 and 7 are then reflected by a mirror 9 onto the cornea 10 of a patient's eye. The scanner 8 consists of a pair of motorized coated mirrors with a 45 degree highly reflecting both the ablative laser beam 2 and the coagulative laser beam 7. The mirror 4 and mirror 9 are highly reflective to the wavelength of the beams 2 and 7. Mirror 5 is coated such that it is highly reflective of laser beam 2 but highly transparent to laser beam 7. The focusing lens 3 has a focal length of about 10-100 cm such that the spot size of the ablative laser beam 2 is about 0.1-0.8 mm on the corneal surface. The

focusing lens 3A also has a focal length about 10-100 cm such that the spot size of the coagulative laser beam 7 is about 0.2-2.0 mm on the corneal surface. In Figure 1, both the ablative and the coagulative lasers beams 2 and 7 are scanned by the scanner 8 over the corneal sclera area of the eye 10 to generate predetermined patterns, as shown in Figure 4. In Figure 1, the said coagulative laser 6 is used to prevent the potential bleeding during the ablation process of the sclera tissue. Typically, the coagulative laser 6 beam 7 has a spot size larger then the ablative laser 1 beam 2 and has an average power in the range of 20-3000 mW, depending upon the size of the focused beam. To achieve an effective coagulation, the temperature increase of the sclera tissue produced by the coagulative laser beam 7 should be in the range of 40-70 degree Centigrade. The preferred embodiment of the laser 1 and 6 includes a pulsed ablative laser with a pulse width less than 200 nanoseconds such as a Er:YAG laser; Er:YSGG laser; an optical parametric oscillation (OPO) at 2.6-3.2 microns; a gas laser with a wavelength of 2.6-3.2 microns; an excimer laser of ArF at 193 nm; a XeCl laser at 308 nm; a frequency-shifted solid state laser at 0.15 - 3.2 microns; a CO laser at about 6.0 microns and a carbon dioxide laser at 10.6 microns. The long pulse coagulative lasers have a pulse longer than 200 nanoseconds of a green laser; or an argon laser; or a Ho:YAG at 2.1 microns; or a Er:glass at 1.54 microns; or an Er:YAG; or an Er:YSGG; or a diode laser at 0.8-2.1 microns, or any other gas lasers at 0.8-10.6 microns. To achieve the ablation of the sclera tissue at the preferred laser spot size of 0.1-0.8 mm requires an ablative laser energy per pulse of about

0.1-5.0 mJ depending on the pulse duration. On the other hand, the coagulative laser should have an average power of about 30 mW for a small spot and about to 3 W for a larger spot.

Referring to Figure 2, an alternative schematic for the coagulative laser 6 is coupled to a fiber 11 for delivery of the beam to the cornea, where a line pattern may be performed by manually scanning the beam over the cornea. Alternatively, a fiber-coupled coagulation laser 6 may be focused by a cylinder lens to form a line spot on the cornea where a typical spot size of 0.2-2.0 mm x 3.0 -5.0 mm is preferred. In Figure 2, the ablative laser 1 has the same schematic as that of Figure 1 where the laser beam 2 is coupled to the scanner 8 and reflected by the mirror 9 onto the cornea. An alternative embodiment of the present invention is to use a cylinder lens to focus the ablative laser 1 to a line spot with a size of 0.1-0.8 mm x 3.0 - 5.0 mm on the corneal surface to eliminate the scanner 8. Another embodiment may use an optical fiber or an articulate arm to deliver both the coagulative and ablative laser beams such that the presbyopia treatment may be conducted manually without the need of a scanner or reflecting mirrors.

Figure 3 shows the lens of a human eye 12 connected to the ciliary body 13 and the sclera 14 by zonule fibers 15. Expansion of the sclera 14 will cause the ciliary muscle to contract and the lens becomes more spherical in topography with a shorter radii of curvature for near objects. The reversed process of ciliary muscle relaxation will cause a longer radii of curvature for distant objects. Therefore, laser ablation of the sclera tissue will increase the accommodation of the ciliary body for the

presbyopic patient to see both near and distance. For efficient sclera expansion, the depth of the laser ablation needs to be approximately 80% - 90% of the sclera thickness which is about 500 - 700 microns. For safety reasons, the ablation depth should not cut through the choroid. It is therefore clinically important that the patient's sclera thickness be measured pre-operatively and the laser ablation depth controlled. A scanning laser is used to control this depth by the number of scanning lines or slots over the selected area at a given set of laser parameters. Pre-operatively, PMMA is used to calibrate the depth of tissue ablation. Alternatively, the surgeon may observe the color change of the ablated sclera tissue to determine when the ablation depth reaches the interface of the sclera and the ciliary.

Figure 4 shows examples of ablation patterns which will cause sclera expansion and increase the accommodation of the presbyopic patient. As shown in Figure 4A, line patterns are conducted between circles 16 and 17 which have diameters of about 8-11 mm and 12-15 mm, respectively. The width of the ablated lines are about 0.1-0.5 mm with a depth of 80%-90% of the sclera. Eight (8) lines are shown in Figure 4A as an example but it can be more or less without departing from the spirit and scope of the invention. Enhancement may be performed by adding more ablation lines. Figure 4B shows a ring pattern with a diameter 18 of about 12-14 mm. A two-ring pattern 19 is shown in Figure 4C where two circles have diameters of about 10 mm and 12 mm, respectively. Another example of an ablation pattern is shown in Figure 4D where the ablation laser is focused to a round spot 20 of about 0.1-0.5 mm in diameter and

scanned over the sclera area to form an eight spot symmetric ring which has a diameter of about 12-14 mm. In all the above described ablative patterns, the coagulative laser described in Figures 1 and 2 simultaneously deliver these patterns such that the sclera tissue may be coagulated as the tissue is being ablated. The preferred spot sizes of the coagulative lasers are larger than that of the ablative laser so that the alignment of the coagulative laser is not critical.

Another embodiment of controlling the ablation area of the sclera area is to use a metal mask which has a plurality of slits each having an approximate dimension of 0.1-0.3 mm x 3.0-5.0 mm. Both of the ablative and coagulative lasers will scan over the mask which is placed on the corneal surface to generate the desired slit pattern on the sclera. In this embodiment using a mask, the small laser spot sizes of 0.1 mm, which may be difficult to achieve, are not needed in order to generate the slit size on the cornea. Laser spot sizes of 0.2-1.0 mm will generate the desired ablation dimension on the sclera after scanning over the mask. Furthermore, the embodiment of using a mask will not require a precise stability of the laser beam path onto the corneal surface. Without using a mask, both the exact laser beam spot size and its stability in propagating would be essential.

Another embodiment of sclera expansion of the present invention is to use diamond knife for the incision of the sclera tissue in the patterns described in Figures 4A, 4B and 4C where the coagulation laser is simultaneously applied onto the cut tissue to prevent bleeding. The incision depth

should be about 80% to 90% of the sclera thickness in order to achieve the effects of sclera expansion. Accordingly, the pre-operative measurement of the sclera thickness is essential for the knife incision procedure and surgeon's skill is more important than that of using an ablative laser, in which the ablation depth of the sclera tissue is well controlled by the numbers of scanning lines in a given pattern. We are able to calibrate the ablation rate of various lasers on the sclera tissue by comparing the clinical data and that of the selected materials including a PMMA plastic sheet.

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from the spirit or essential characteristics of the present invention. Accordingly, the embodiments described herein are to be considered to be illustrative and not restrictive.

I claim:

1. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera comprising the steps of :

selecting a pulsed ablation laser having a pulsed output beam of predetermined wavelength and an energy per pulse of between 0.1 - 5 mJ on the surface of the cornea;

selecting a beam spot controller mechanism for reducing and focusing said selected ablative laser's output beam onto a predetermined spot size on the surface of the cornea;

selecting a scanning mechanism for scanning said ablative laser output beam;

coupling said ablative laser beam to a scanning device for scanning said ablative laser over a predetermined area of the corneal sclera; and

controlling said scanning mechanism to deliver said ablative laser beam in a predetermined pattern in said predetermined area onto the surface of the cornea to photoablate the sclera, whereby a presbyopic patient's vision is corrected by expansion of the sclera.

2. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed ablative laser having a predetermined wavelength between 0.15 - 0.32 microns.

3. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed ablative laser having a wavelength between 2.6 and 3.2 microns.

4. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a Q-switched solid state laser having a pulse duration shorter than 200 nanoseconds.

5. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed gas laser having a pulse duration shorter than 200 nanoseconds.

6. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which said the step of selecting a beam spot controller includes selecting a pulsed ablative laser having a focusing lens with focal length of between 10 and 100 cm selected to obtain a predetermined laser beam spot size having a diameter of between 0.1 and 0.8 mm on the corneal surface.

7. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by 6g ablating the sclera in accordance with claim 1 in which the step of selecting a beam spot controller includes selecting beam spot controller having a focusing lens with cylinder focal length of between 10 and 100 cm to obtain a laser beam spot having a line size of about 0.1-0.8 mm x 3-5 mm on the corneal surface.

8. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a scanning mechanism includes selecting a scanning mechanism having a pair of reflecting mirrors mounted to a galvanometer scanning mechanism for controlling said laser output beam into a predetermined overlapping pattern.

9. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 8 in which the step of selecting said scanning mechanism includes selecting a scanning mechanism having an overlapping pattern overlapping from 20 to 80% within the selected area of the sclera.

10. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 1 including the steps of:

selecting a coagulative laser having a pulsed output beam of predetermined wavelength; and

directing said selected coagulative laser onto those areas of the sclera photoablated with the selected pulsed ablation laser.

11. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by ablating the sclera in accordance with claim 10 including the steps of:

selecting a metal mask having at least on slit therein; and

positioning the selected mask over the cornea surface for scanning the ablation laser and the coagulative laser thereover for controlling the ablation slit pattern on the sclera.

12. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue including the steps of:

selecting an ablation laser having an output beam of predetermined wavelength for ablating the surface of the cornea;

ablating a predetermined area of the cornea sclera with the output beam from said ablation laser;

selecting a coagulative laser having an pulsed output beam of predetermined wavelength having an average power of between 20-3000 mW on the surface of the cornea;

selecting a beam spot controller mechanism for reducing and focusing said coagulative laser beam to a predetermined spot size on the corneal surface;

selecting a scanner for scanning said coagulative laser output beam;

coupling said coagulative laser beam onto a scanner for scanning said coagulative laser beam over a predetermined area of the corneal sclera which has been ablated by said ablation laser;

controlling the scanner to deliver said coagulative laser output beam in a predetermined pattern onto a plurality of positions on the corneal surface to coagulate the ablated areas of the sclera, whereby bleeding in said ablated tissue is reduced by the said coagulation laser beam.

13. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said predetermined wavelength is between 0.5 and 3.2 microns.

14. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said predetermined wavelength is between 5.5-10.6 microns.

15. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said coagulative laser is a continuous wave laser.

16. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selected coagulative laser is a long pulse laser having a pulse duration longer than 200 nanoseconds.

17. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said step of selecting a beam spot controller includes selecting a focusing lens having a focal length of between 10 and 100 cm. to obtain a predetermined laser beam spot size having a diameter between 0.2-2.0 mm on the corneal surface.

18. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selecting beam spot controller includes a focusing lens having a focal length of between 10 and 100 cm selected to obtain a predetermined laser beam spot having a line size of about 0.2-2.0 x 3-5 mm on the corneal surface.

19. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which the step of selecting a scanning mechanism includes selecting a scanning mechanism having a pair of reflecting mirrors mounted to a galvanometer scanner for controlling said coagulative laser output beam into an overlapping pattern following said ablative laser output beam ablating surface tissue on the corneal surface.

20. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 19 in which said overlapping pattern includes an overlap of between 20 and 80% in a pattern defined on the corneal surface by said ablative laser.

21. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said ablative laser has a wavelength between 0.5-3.2 microns and a pulse width shorter than 200 nanoseconds delivered to the surface of the cornea by an optical fiber.

22. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selected coagulative laser has a wavelength of between 0.5-10.6 microns, and a pulse width longer than 200 nanoseconds delivered to the surface of the cornea by an optical fiber to prevent tissue bleeding.

23. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue expanded by a knife to prevent bleeding in the tissue including the steps of:

cutting a predetermined area of the cornea sclera with a knife;

selecting a coagulative laser having an pulsed output beam of predetermined wavelength having an average power of between 20-3000 mW on the surface of the cornea;

selecting a beam spot controller mechanism for reducing and focusing said coagulative laser beam to a predetermined spot size on the corneal surface;

selecting a scanner for scanning said coagulative laser output beam;

coupling said coagulative laser beam onto a scanner for scanning said coagulative laser beam over a predetermined area of the corneal sclera which has been cut with said knife;

controlling the scanner to deliver said coagulative laser output beam in a predetermined pattern onto a plurality of positions on the corneal surface to coagulate the cut areas of the sclera, whereby bleeding in said cut tissue is reduced by the said coagulation laser beam.

24. A laser beam ophthalmological surgery method for treating presbyopic in a patent's eye by coagulating sclera tissue expanded by a knife to prevent bleeding in the tissue in accordance with claim 23 in which the selected coagulative laser has a wavelength of between 0.5 and 10.6 microns and a pulse width longer than 200 nanoseconds.

TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING A DUAL-LASER SCANNING SYSTEM

ABSTRACT OF THE DISCLOSURE

Presbyopia is treated by a method which uses ablative lasers to ablate the sclera tissue and increase the accommodation of the ciliary body. Tissue bleeding is prevented by a dual-beam system which consists of ablative and coagulative lasers. The preferred embodiments of the present invention include a short pulse ablative laser (pulse duration less than 200 nanoseconds) having a wavelength of between 0.15 and 3.2 microns and a long pulse (longer than 200 nanoseconds) coagulative laser having a wavelength range of between 0.5 and 10.6 microns. A scanning system is proposed to perform various patterns on the sclera area of the cornea to treat presbyopia and to prevent other eye disorder such as glaucoma. Laser parameters are determined for accurate sclera expansion.

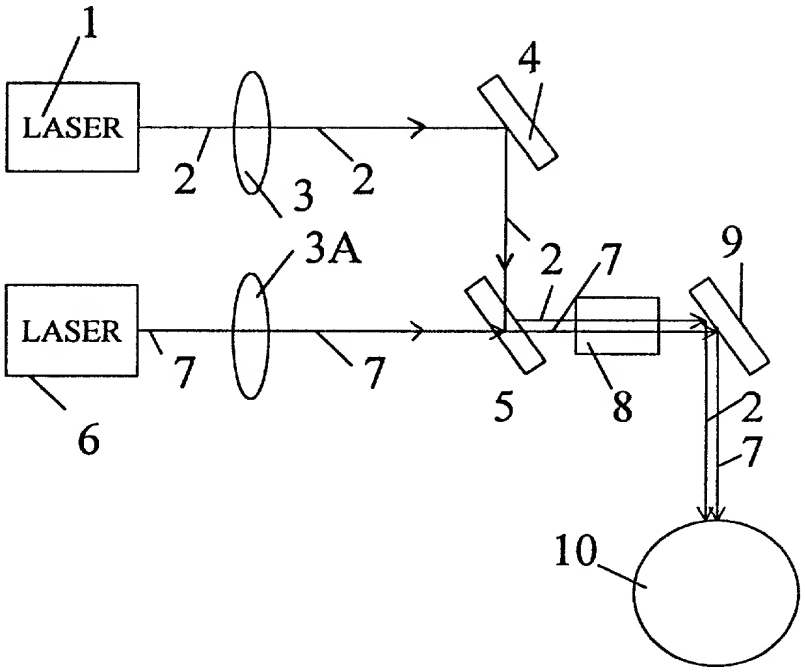
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FIG. 1

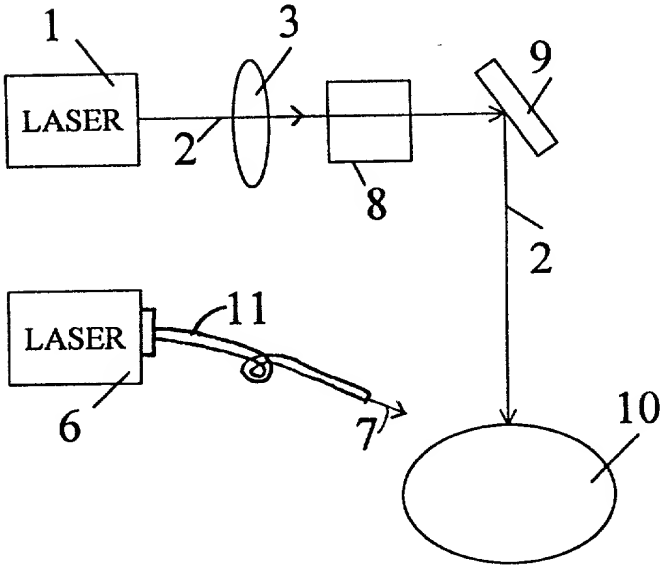
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FIG. 2

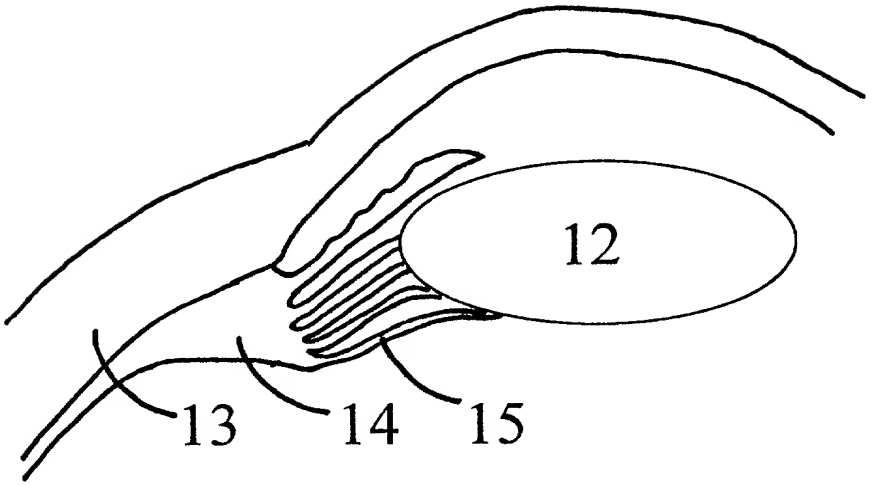

FIG. 3

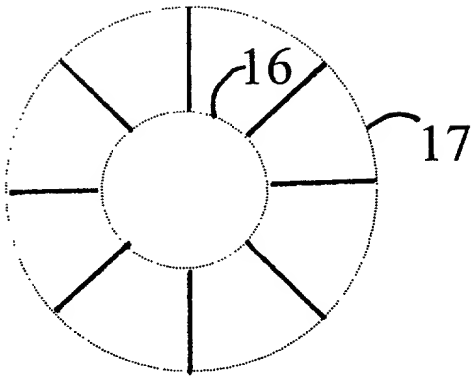

FIG. 4A

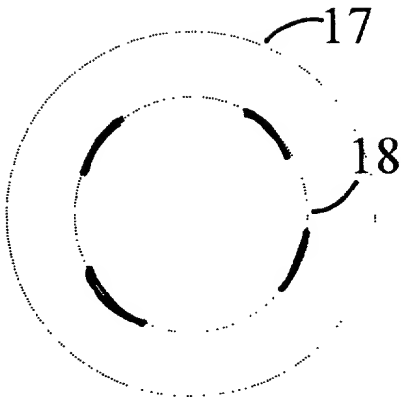

FIG. 4B

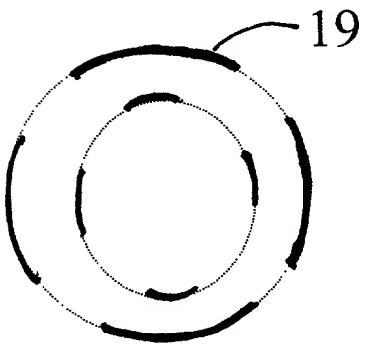

FIG. 4C

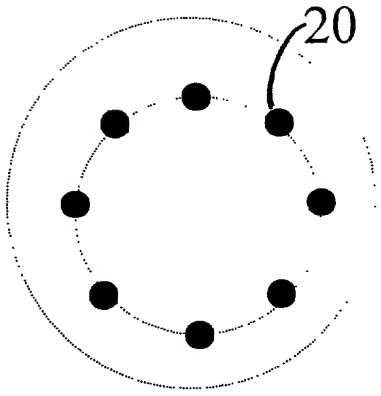

FIG. 4D

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	98-5295
First Named Inventor	J.T. Lin
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING A DUAL-LASER SCANNING SYSTEM

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
William M. Hobby, III	24,167		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

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Country	U.S.A.	Telephone	(407) 644-8888	Fax	(407) 645-3200

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
J.T.	Lin

Inventor's Signature						Date	11/6/98
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Post Office Address							
City	Winter Springs	State	FL	ZIP	32708	Country	U.S.

☐ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto